UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: AFLIBERCEPT PATENT LITIGATION MDL No. 3103

TRANSFER ORDER

Before the Panel:* Common plaintiff Regeneron Pharmaceuticals, Inc., moves under 28 U.S.C. § 1407 to centralize this litigation in the Northern District of West Virginia. The litigation consists of six actions, as listed on Schedule A. One action is pending in the Central District of California and five in the Northern District of West Virginia, where all are assigned to Chief Judge Thomas S. Kleeh. All defendants oppose the motion.

On the basis of the papers filed and the hearing session held, we find that these actions involve common questions of fact and that centralization in the Northern District of West Virginia will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation. All actions were brought under the Biologics Price Competition and Innovation Act (BPCIA).[1] In each action, Regeneron alleges that the defendant infringed a common set of

* Judges Nathaniel M. Gorton and David C. Norton did not participate in the decision of this matter.

[1] The Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010), was enacted to expedite the entry of follow-on biologic drugs into the market. Biologic drugs are larger-molecule drugs or vaccines that are produced by manipulating a living tissue or microorganism, such as a virus or protein. *See, e.g.,* Kate S. Gaudry, *Exclusivity Strategies and Opportunities in View of the Biologics Price Competition and Innovation* Act, 66 FOOD & DRUG L.J. 587, 587 & n.1 (2011). Submitting an abbreviated Biologics License Application (aBLA) constitutes a statutory act of infringement that creates subject-matter jurisdiction for a district court to resolve any disputes regarding patent infringement or validity prior to the biosimilar drug's being sold. *See, e.g., Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1, 8 (2017). Under 42 U.S.C. § 262(*l*)(2)(A), an aBLA applicant must provide its application and manufacturing information to the branded drug sponsor within 20 days of the date the U.S. Federal Drug Administration notifies the applicant that it has accepted the aBLA for review. This commences an exchange between the applicant and the branded drug sponsor of lists of potentially relevant patents and the companies' respective arguments regarding those patents. *Id.* § 262(*l*)(3). The BPCIA provides two paths for patent litigation. First, the parties may negotiate to identify patents on the lists for immediate litigation or, if agreement is not reached, the branded drug

(continued . . .)

thirteen U.S. patents covering its ophthalmic drug, Eylea®, by submitting aBLAs and seeking to market their follow-on biologic products.[2] Included among those thirteen patents is one—the '865 Patent—that already has been held valid and infringed by Judge Kleeh after trial in the first-filed Northern District of West Virginia *Mylan* action. Common factual questions will include whether the proposed biosimilar products infringe the patents, the evidence related to claim construction, and patent validity considerations such as the level of ordinary skill in the art, the scope and content of the prior art, and obviousness. Centralization will avoid the risk of duplicative discovery and prevent inconsistent rulings as to claim construction, patent validity, and other issues.

All defendants oppose the motion. They argue that each action involves dozens of patents—a total of 63 across all actions—and that many non-overlapping patents are asserted against each defendant. In addition, some of the common patents relate to manufacturing methods, which defendants claim are unique to each defendant; thus, they argue, they may have different invalidity and non-infringement defenses even to the same patents. Defendants also contend that, because they are competitors and their manufacturing methods are highly confidential, if the litigation is centralized, special discovery protections will be necessary. Defendants maintain that these complexities make this BPCIA litigation significantly different from litigation under the Hatch-Waxman Act[3] that the Panel typically centralizes and would result in an unmanageable MDL. Given the relatively small number of involved actions, they argue, centralization is not appropriate.

These arguments are not persuasive. Regeneron asserts a common set of thirteen patents in every action, and every patent asserted against Amgen also is asserted against at least one of the Northern District of West Virginia defendants. Judge Kleeh already has held a *Markman* hearing and bench trial in the first-filed *Mylan* action regarding certain patents, including two of the patents that are asserted against all defendants, and additional patents that remain to be litigated in *Mylan* also are asserted against Amgen and the defendants in the other Northern District of West Virginia cases. According to Regeneron, seven patents are at issue in the preliminary injunction proceedings currently underway in four of the Northern District of West Virginia actions, and five of the patents to be asserted in preliminary injunction proceedings against Amgen also are asserted

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sponsor may bring an action alleging infringement of all patents on the lists. *Id.* § 262(*l*)(6). Second, when a biosimilar applicant gives the branded drug sponsor 180-days' notice that it intends to begin commercially marketing the biosimilar product, as required under § 262(*l*)(8)(A), the branded drug sponsor may seek a preliminary injunction to prevent the marketing of the biosimilar product. *Id.* § 262(*l*)(8)(B).

[2] The thirteen patents common to all actions are: U.S. Patent Nos. 9,222,106; 9,254,338; 9,816,110; 10,130,681; 10,415,055; 10,464,992; 10,669,594; 10,888,601; 11,084,865 (the '865 Patent); 11,066,458; 11,104,715; 11,253,572; and 11,306,135.

[3] The Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (1984).

in the preliminary injunction proceedings against at least one of the West Virginia defendants. The '865 patent, a formulation patent, which already has been found valid and infringed by Mylan, is asserted against *all* defendants and, according to Regeneron, will be central in every case. Even if there is some variation among defendants' defenses to certain patents, it seems far more efficient to allow a single court to construe the patents at issue and to decide whether injunctive relief is warranted.

Defendants also oppose transfer of the Central District of California *Amgen* action on the ground that it is in a different procedural posture than the Northern District of West Virginia litigation. They complain that transfer might delay progress in the *Mylan* action and note that it is too late to include *Amgen* in the preliminary injunction proceedings underway in the Northern District of West Virginia. Again, these arguments are not convincing. Chief Judge Kleeh, who presides over all five West Virginia actions, has rejected defendants' request for expedited proceedings in *Mylan*, pointing out that the '865 Patent will not expire until June 2027; hence, there seems little reason to believe that transferring *Amgen* to the Northern District of West Virginia would cause significant delay in *Mylan*. Even though preliminary injunction proceedings in *Amgen* necessarily may trail those in the West Virginia actions, given the overlap in the involved patents, transfer of *Amgen* still will provide efficiencies for the parties and preserve judicial resources.

Finally, several of the Northern District of West Virginia defendants contend that the motion should be denied because Regeneron filed its Section 1407 motion, and sought to have it heard on an expedited basis,[4] in an attempt to circumvent a possible unfavorable decision on their motions to dismiss for lack of personal jurisdiction. In support, they cite, *inter alia*, *In re Henry L. Klein Litigation*, 923 F. Supp. 2d 1373 (J.P.M.L. 2013). The *Klein* case is inapposite. In *Klein*, the plaintiff filed an action in District of the District of Columbia; then, after the defendant moved to dismiss that action for lack of personal jurisdiction, plaintiff filed an identical action in the Middle District of Florida and sought to centralize the actions in the District of the District of Columbia. *Id.* at 1374. Here, Regeneron sought to transfer the *Amgen* action on an expedited basis so that it could be included in the condensed schedule for preliminary injunction proceedings that had been set in the Northern District of West Virginia actions. Regeneron attached to its motion the court's scheduling order, which discussed the personal jurisdiction motions to dismiss, and thus does not appear to have attempted to conceal from the Panel that defendants intended to challenge personal jurisdiction in the Northern District of West Virginia.

Chief Judge Thomas S. Kleeh is the obvious choice to preside over this litigation. He already has presided over significant proceedings, including trial as to one patent asserted in the *Amgen* action, and currently is considering preliminary or permanent injunction motions involving additional overlapping patents in the Northern District of West Virginia actions. A hearing as to those motions is scheduled on May 2, 2024.

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[4] On January 11, 2024, with its Section 1407 motion, Regeneron filed a motion for expedited consideration of the motion. The Panel denied that motion on January 12, 2024.

IT IS THEREFORE ORDERED that the action listed on Schedule A and pending outside the Northern District of West Virginia is transferred to the Northern District of West Virginia and, with the consent of that court, assigned to the Honorable Thomas S. Kleeh for coordinated or consolidated pretrial proceedings.

PANEL ON MULTIDISTRICT LITIGATION

Karen K. Caldwell
Chair

Matthew F. Kennelly
Dale A. Kimball

Roger T. Benitez
Madeline Cox Arleo

IN RE: AFLIBERCEPT PATENT LITIGATION MDL No. 3103

SCHEDULE A

Central District of California

REGENERON PHARMACEUTICALS, INC. v. AMGEN, INC., C.A. No. 2:24−00264

Northern District of West Virginia

REGENERON PHARMACEUTICALS, INC. v. MYLAN PHARMACEUTICALS, INC., C.A. No. 1:22−00061
REGENERON PHARMACEUTICALS, INC. v. CELLTRION, INC., C.A. No. 1:23−00089
REGENERON PHARMACEUTICALS, INC. v. SAMSUNG BIOEPIS, CO., LTD., C.A. No. 1:23−00094
REGENERON PHARMACEUTICALS, INC. v. FORMYCON AG, C.A. No. 1:23−00097
REGENERON PHARMACEUTICALS, INC. v. SAMSUNG BIOEPIS CO., LTD., C.A. No. 1:23−00106